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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,018	09/20/2001	John G Cumming	P 0282964	4357
9629	7590	01/29/2003	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			RAO, DEEPAK R	
ART UNIT	PAPER NUMBER			
1624	12			

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/937,018	Applicant(s) Cumming
Examiner Deepak Rao	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on 9/20/01 and 1/23/03 \_\_\_\_\_

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

4)  Claim(s) 1-10, 12, and 13 \_\_\_\_\_ /are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ /are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ /are allowed.

6)  Claim(s) 1, 4, 9, 10, 12, and 13 \_\_\_\_\_ /are rejected.

7)  Claim(s) 2, 3, and 5-8 \_\_\_\_\_ /are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). 9  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 & 11 6)  Other:

<b>Interview Summary</b>	Application No. <b>09/937,018</b>	Applicant(s) <b>Cumming</b>
	Examiner <b>Deepak Rao</b>	Art Unit <b>1624</b>

All participants (applicant, applicant's representative, PTO personnel):

(1) Deepak Rao (3) \_\_\_\_\_  
 (2) Mr. Donald Bird, Applicant's Representative (4) \_\_\_\_\_

Date of Interview Jan 16, 2003

Type: a) Telephonic b) Video Conference  
 c) Personal [copy is given to 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No. If yes, brief description:

\_\_\_\_\_

\_\_\_\_\_

Claim(s) discussed: Pending

Identification of prior art discussed:

None.

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

A telephonic restriction requirement was given, Group I drawn to formula (I) wherein G is N and Group II drawn to compounds of formula (II) wherein G is C. Mr. Bird indicated that a response along with a preliminary amendment will be filed.

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached

**DEEPAK RAO**  
**PRIMARY EXAMINER**  
**ART UNIT 1624**

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

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## **DETAILED ACTION**

Claims 1-12 are pending in this application.

### ***Election/Restrictions***

The following restriction was presented telephonically on January 16, 2003.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, drawn to compounds of formula (I) wherein G = N, corresponding composition and method of use.

Group II, claim(s) 1 and 9-12, drawn to compounds of formula (I) wherein G = CH or C(CN), corresponding composition and method of use.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The compounds of Groups I-II are drawn to structurally dissimilar compounds. They are made independently and used independently. They would be expected to raise different issues of patentability and they are not considered to be functional equivalents. Art which may anticipate

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or render obvious one of the groups would not necessarily do the same for the other group. The inventions of Groups I-II do not share the same technical features as required by PCT Rules 13.2 and 13.3 and therefore, Unity of Invention does not exist.

Applicant's election of Group I in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The preliminary amendment filed on January 23, 2003 is acknowledged. After the entry of the amendment, **claims 1-10 and 12-13 are currently pending in this application.**

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 recites 'compound of Formula (I)', however, does not disclose the formula in the claim. A claim to be independent must contain all limitations within the claim or should be rewritten in dependent form. Insertion of -- according to claim 1 -- following "formula(I)" is suggested.

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***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al. (J. Med. Chem. 1995). The reference discloses the compound 7-amino-4-[(3-acetamidophenyl)amino]pyrido[4,3-d]pyrimidine (compound no. 7z in Table 1, page 3782). The reference teaches that the compound is useful as a therapeutic agent for malignant diseases, etc. see page 3780, col. 1, first paragraph. The instant claim reads on the reference because the instant claim is drawn to 'a method of treating a disease or medical condition mediated by cytokines' and the specification on pages 1-2, provides that the diseases include malignant diseases, tumor invasiveness, tumor metastasis, etc. (see page 2, lines 15-16).

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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1. Claims 1, 9, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (J. Med. Chem. 1995). The reference discloses the compound, 7-amino-4-[(3-acetamidophenyl)amino]pyrido[4,3-d]pyrimidine (compound no. 7z in Table 1, page 3782) which has been excluded from the instant claims, see the last line of claim 1. The instant claims, however, include compounds that are homologs of the reference compounds, i.e., compounds that differ by a -CH<sub>2</sub> group (i.e., adding or removing a methyl substituent to or from the reference compound no. 7z, e.g., when the 3-substituent on the phenyl ring is -NH-C(O)-CH<sub>2</sub>-CH<sub>3</sub>, etc.). The reference teaches that the compound is useful as a therapeutic agent for malignant diseases, see page 3780. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such structurally homologous compounds would be expected to possess similar utilities. It has been held that compounds that are structurally homologous to prior art compounds are *prima facie* obvious, absent a showing of unexpected results. *In re Haas*, 60 USPQ 544 (CCPA 1944); *In re Henze*, 85 USPQ 261 (CCPA 1950). *In re Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904 (Fed. Cir. 1990).

2. Claims 1, 9-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ugarkar et al., WO 96/40706. The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula 1 wherein G is H, p is 0, X is aryl substituted by acylamino. The compounds are taught to be useful as therapeutic agents for the treatment of diseases such as arthritis, etc., see page 43. Further, the reference discloses a specific compound having a 4-trifluoroacetamido substituent on the anilino group attached to the

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4-position of the bicyclic ring system, see compound #129, page 24. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference because the definition of R<sup>1</sup> in the instant claims includes D-E- wherein D is heterocycl and E is a bond. For example, the instant compounds are structural isomers of the reference disclosed compound #129. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render *prima facie* obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

3. Claims 1, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiesenfeldt et al., EP 447891. The reference teaches compounds that are positional isomers of instantly claimed compounds. See the compound of the structural formula (I) in page 2 and the specific compound 249 in Table 1, page 20 wherein R<sup>2</sup> is NH-C<sub>6</sub>H<sub>4</sub>-(4)-NH-COCH<sub>3</sub>. The reference compounds are taught to be useful as insecticides, herbicides, etc., see the abstract.

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The instantly claimed compounds are positional isomers of the reference compounds because the instant compounds differ by the position of the -NH-COCH<sub>3</sub> substituent on the phenyl portion of the anilino group attached to the bicyclic ring system. The instant compounds have the substituent at the 3-position as compared to the reference wherein the substituent is at the 4-position. It would have been obvious to one having ordinary skill in the art at the time of the invention to prepare the instantly claimed compounds because they are isomers of the reference compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such structurally isomeric compounds are suggestive of one another and would be expected to share similar properties and therefore, the same use as taught for the reference compounds. It has been held that a compound which is isomeric with a compound of prior art is *prima facie* obvious absent unexpected results. *In re Finley*, 81 USPQ 383 (CCPA 1949); *In re Norris*, 84 USPQ 458 (CCPA 1950). *In re Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904 (Fed. Cir. 1990).

### ***Claim Objections***

Claims 2, 3 and 5-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Receipt is acknowledged of the Information Disclosure Statement filed on January 3 and 23, 2003 and copies are enclosed herewith.

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Receipt is also acknowledged of the International Search report and the cited references have been considered.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Deepak Rao  
Primary Examiner  
Art Unit 1624

January 26, 2003